

### REMARKS

Claims 2, 3, 5, 12, 14 to 22 and 42 are pending and under examination. Claim 2 has been amended to recite that the pharmaceutical composition comprises a biopolymer composition consisting of (i) through (iii). Claim 2 has also been amended to further improve clarity. The specification has been amended to include a paragraph in compliance with 35 U.S.C. 103(c). These amendments are supported throughout the specification and add no new matter to the specification.

### Interview Summary

Applicants thank Examiner Lucas for his time to conduct a telephonic interview with the undersigned and Laurie Butler Lawrence on December 7, 2006. The prior art and potential claim amendments were discussed. The amendments described herein seek to amend the claims along the lines discussed during the interview.

### Objection to the Claims

Claim 5 has been objected to for allegedly failing to further limit the subject matter of claim 2. For reasons unrelated to the present rejection, applicants have amended claim 2 such that it no longer recites the phrase "consisting of a cephalosporin," thereby obviating the present objection. Accordingly, applicants request that this objection be reconsidered and withdrawn.

### Obviousness-Type Double Patenting

Claims 2, 3, 5, 12, and 14 to 22 remain rejected for an alleged violation of the judicially created doctrine of obviousness-type double patenting over claims 1, 8-11, 14-21, 24, 31, and 32-34 of U.S. Patent No. 6,248,360.

Applicants maintain their position that this rejection is improper. However, in the interest of moving this application toward allowance, applicants have taken the steps necessary to establish that the subject matter recited in the present claims was generated by or on the behalf of parties to a joint research agreement within the meaning of 35 U.S.C. 103(c)(3). To that end,

applicants provide herewith (1) a Statement in compliance with 35 U.S.C. 103(c)(2); (2) an amendment to the specification that recites the names of the parties to the joint research agreement and the effective date and field of the agreement; and (3) the processing fee required under 37 C.F.R. 1.71(g).

Applicants request that the Office consider applicants' submissions and find that applicants have successfully invoked the Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) with respect to U.S. Patent No. 6,248,360. Having established that applicants have successfully invoked the CREATE Act, U.S. Patent No. 6,248,360 should properly be viewed as being commonly owned with the instant application in accordance with MPEP §804.03(II)(B). Accordingly, to obviate the present double patenting rejection, applicants request that the Office consider and accept the terminal disclaimer submitted herewith.

In view of the above, applicants request that the present rejection be reconsidered and withdrawn.

#### Rejection under 35 U.S.C. 103(a)

Claims 2, 3, 5, 12, and 14-22 remain rejected under 35 U.S.C. 103(a) as allegedly obvious over U.S. Patent 6,458,287 (Scott) in view of WO 98/30207 (Watts). In maintaining the rejection, the Office Action states (at page 5):

The Applicant traverses the rejection on the basis that the claims have been amended to read on a composition comprising "an antimicrobial agent consisting of a cephalosporin," and that the Scott reference teaches that in order for such cephalosporin agents to be incorporated into the microparticles, they are first attached to a macromolecule. The Applicant asserts that the closed language of the claims excludes embodiments wherein the drug is so attached. This argument is not found persuasive.

The claims read on a composition comprising a antimicrobial agent, wherein the antimicrobial agent consists of the cephalosporin. Thus, while the claim provides closed language with respect to the antimicrobial agent used, it is not closed with respect to other constituents of the claimed composition. The amended claim language therefore does not exclude the use of the macromolecules of Scott, which are not themselves antimicrobial agents. The rejection is therefore maintained for the reasons above, and the reasons of record.

Applicants do not agree that the applicants' previous amendments and arguments do not obviate the present rejection. Accordingly, applicants reiterate and incorporate herein by reference their arguments from their Amendment in Reply to Action of February 22, 2006. However, in the interest of moving the present application toward allowance, and as discussed during the interview, applicants have amended claim 2 to recite a pharmaceutical composition for oral delivery of a cephalosporin comprising (a) a composition consisting of (i) a biopolymer; (ii) at least one cephalosporin entrained within or ionically bound to the biopolymer; (iii) at least one metal cation entrained within or ionically bound to the biopolymer or the cephalosporin; and b) an absorption enhancer.

Applicants submit that these amendments to the claims should address the Office's concerns and exclude the compositions of Scott. Specifically, the compositions disclosed in Scott require a macromolecule that has or is capable of having tertiary and quaternary structure. Compounds lacking such structure, like a drug or other pharmaceutical, are only incorporated into the microsphere by attachment to a macromolecule. Thus, Scott requires that when compounds such as cephalosporins, which lack tertiary or quaternary structure, are used, the active agent is that compound in conjunction with a macromolecule to provide an agent with the required structure. The antimicrobial agent recited in the claims, like the drug and pharmaceutical agents disclosed in Scott, lacks the tertiary and quaternary structure necessary to be incorporated in the microspheres of Scott. Moreover, the closed language, consisting of, precludes compositions disclosed by Scott, i.e., an active agent having tertiary or quaternary structure based on the combination of an antimicrobial and a macromolecule. Therefore Scott does not disclose or suggest an antimicrobial agent ionically bound to a biopolymer as required by the claims. Applicants therefore reiterate that neither Scott nor Watts, alone or in combination, render the present claims obvious and request that the present rejection be reconsidered and withdrawn.

Claims 2, 3, 5, 12, 14-22, and 42 remain rejected as allegedly obvious over Scott in view of Watts and further in view of U.S. Patent No. 5,783,561 (Horwitz). In maintaining the rejection, the Office reiterates the reasoning quoted above. Again, applicants do not agree that

the applicants' previous amendments and arguments do not obviate the present rejection. Nevertheless, as discussed above, applicants have amended the claims to address the Office's concerns and submit that no combination of Scott, Watts, and Horwitz can support a case of obviousness against the amended claims. Thus, applicants request that the present rejection be reconsidered and withdrawn.

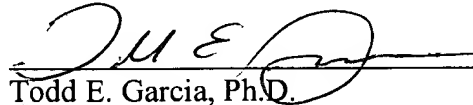
### CONCLUSION

Applicants ask that all rejections and objections be reconsidered and withdrawn. Enclosed is a \$510 check for the Petition for Extension of Time fee for a three month extension. Also enclosed is a \$130 check for the processing fee for amending the specification as required under 37 C.F.R. 1.71(g). Please apply any other charges or credits to deposit account 06-1050 referencing Attorney Docket No. 19916-003001.

Respectfully submitted,

Date: \_\_\_\_\_

3/13/07



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